JUN 2 7 2003

K030682

June 25, 2003

SECTION 4

510(k) Summary of Safety and Effectiveness

4.1 Manufacturer and Submitter Information:

BioForm Inc.
4133 Courtney Road, #10
Franksville, WI 53126
Telephone: (262) 835-9800
Contact: William G. Hubbard
Summary Preparation Date: June 25, 2003

4.2 Device Trade Name:	Calcium Hydroxylapatite Implant
Common Name:	Synthetic Bone Graft Material
Classification Name:	Bone Filling and Augmentation Material
Device Class:	Unclassified
Product Code:	LYC
Medical Specialty:	Dental (DE)
Performance Standards:	No applicable mandatory performance standards or special controls exist for this device.

4.3 Substantial Equivalent Predicate Device:

The following are the predicate devices that are substantially equivalent to the Calcium Hydroxylapatite Implant:

K882682	Calcitite Calcitek, Inc., 4125-B Sorrento Valley Boulevard, San Diego, CA 92121
K852742	Osteograf AR Alveolar Ridge Hydroxylapatite 18-40 Coors Biomedical Company, 12860 West Cedar Drive, Lakewood, CO 80228
K852765	HA-2000 Orthomatrix, Inc., 6968 Sierra Court, Dublin CA 94568
K992416	Perioglas-BioGlass Bone Graft Particulate U.S. Biomaterials Corp., One Progress Boulevard, Alachua, FL 32615
K000149	Novabone-Bioglass Bone Graft Particulate U.S. Biomaterials Corp., One Progress Boulevard, Alachua, FL 32615
K952922	Biogran Bioactive Glass Synthetic Bone Graft Material

	Orthovita Co., 212 Carnegie Center Drive, Suite 206, Princeton, NJ 08540
K921468	PermaMesh Hydroxylapatite Matrix CeraMed Corp., 12860 West Cedar Drive, Lakewood, CO 80228
K862061	Osteograf/AR+ Permaridge Hydroxylapatite, 18-40 Coors Biomedical Co., 12860 West Cedar Drive, Suite 210, Lakewood, CO 80228
K910432	HAPSET Hydroxylapatite Bone Graft Plaster Lifecore Biomedical, Inc., 1050 Connecticut Avenue, N.W. Washington Square, Suite 1100, Washington, D.C. 20036

Calcium Hydroxylapatite Craniofacial Implants are identical to Coaptite® Laryngeal Augmentation System (K013243) and Coaptite® Tissue Marker (K012955) manufactured by BioForm Inc. The Calcium Hydroxylapatite Implant is substantially equivalent to the predicate devices sited above.

4.4 Device Description:

Calcium Hydroxylapatite Implant is a sterile, non-pyrogenic, flexible, semi-solid, cohesive paste containing calcium hydroxylapatite particles. Calcium Hydroxylapatite Implant is intended to fill and/or augment dental intraosseous and oral/maxillofacial defects. Calcium Hydroxylapatite Implant contains calcium hydroxylapatite particles in a pasty gel of glycerin, water and sodium carboxymethylcellulose that acts as a binder for the particles. The calcium hydroxylapatite meets ASTM F1185. The gel ingredients are pharmaceutical grade excipients and are listed as GRAS materials.

4.5 Intended Use:

Calcium Hydroxylapatite Implant is intended to fill and/or augment dental intraosseous and oral/maxillofacial defects including:

- Periodontal Defects
- Ridge Augmentation
- Extraction Sites
- Craniofacial Augmentation
- Cystic Defects

4.6 Technological Characteristics:

Calcium Hydroxylapatite Implant (CaHA Implant) is a paste of calcium hydroxylapatite (calcium phosphate) particles and a binder. The binder is resorbable and acts to hold the particles together. The resorption of the binder provides the controlled porosity for bone ingrowth. These 'pores' are the interconnected pathways around and between the calcium hydroxylapatite particles that are non-absorbable. The calcium hydroxylapatite particles provide

an osteoconductive scaffold for bone infiltration. The CaHA Implant functions as an osteoconductive scaffold for bone infiltration, the same mechanism of action as the predicate devices. The premixed and ready to use characteristic facilitates the delivery of CaHA Implant by allowing direct and controlled deposition using the syringe. This may be enhanced for implantation in difficult to access locations by the placing of a needle on the syringe. In addition, the binder serves to reduce or prevent migration during the application and in the post-operative healing period prior to incorporation of the particles by tissue ingrowth.

The Calcium Hydroxylapatite Implant (CaHA Implant) is substantially equivalent in composition and intended use to the predicate devices. The CaHA Implant and the predicate devices are all intended to fill and/or augment dental intraosseous and oral/maxillofacial defects. All of the predicate devices and the CaHA Implant are composites of resorbable (binder) and non-resorbable (calcium phosphate particles) components. The predicate devices use sterile water, saline, the patient's own blood or absorbable sutures to bind the particles together to facilitate delivery of the particles and minimize migration of the particles from the implant site. These other binding agents are resorbed within weeks or months depending upon the used and how it is prepared. All of these are also substantially equivalent in their mechanism of action as they provide a calcium phosphate particle that provides an osteoconductive scaffold for bone infiltration. The bone infiltration provides the final form of the implant.

The principal component of the Calcium Hydroxylapatite Implant, calcium hydroxylapatite is identical to the calcium hydroxylapatite used in most of the predicates and is very similar to the calcium phosphate glasses used in the rest of the predicate devices. All of these meet the same biocompatibility requirements. It is substantially equivalent in terms of biocompatibility and biological mechanism of action in that all of these products utilize tissue ingrowth to support and sustain augmentation.

In terms of risk versus benefit, BioForm believes that the CaHA Implant has obvious advantages compared to the predicate devices. The CAHA implant is provided as a sterile and ready to use paste that is more convenient for the physician, minimizes the potential for contamination during the mixing processes required by other devices, eliminates the risk and pain associated with drawing blood and is more convenient to place. The CaHA Implant also is convenient to use because the amount of filling or augmentation can be easily controlled through direct application.

4.7 Conclusion:

In summary, Calcium Hydroxylapatite Implant is substantially equivalent to the cited predicate devices and, in some instances, identical to certain predicate devices. All have the same intended use designed to fill and/or augment dental intraosseous and oral/maxillofacial defects. The components used in the Calcium Hydroxylapatite Implant and the predicate devices are biocompatible, based on the history use in many medical devices as well as from preclinical testing and clinical experience. All function as composites that utilize a resorbable binder and a non-resorbable calcium phosphate particulate. The binder facilitates placement and the particles function as an osteoconductive matrix. All reach their final form after tissue infiltration. The Calcium Hydroxylapatite Implant is substantially equivalent in intended use, technical characteristics and are as safe as the predicate devices cited.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 27 2003

Mr. William G. Hubbard
BioForm Incorporated
4133 Courtney Road, #10
Franksville, Wisconsin 53126

Re: K030682
Trade/Device Name: Calcium Hydroxylapatite Implant
Regulation Number: None
Regulation Name: Bone Filling and Augmentation Material
Regulatory Class: Unclassified
Product Code: LYC
Dated: June 9, 2003
Received: June 10, 2003

Dear Mr. Hubbard:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4613. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Susan Runner

Susan Runner, DDS, MA
Interim Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION 2

Indications for Use/Intended Use Statement

510(k) Number (if known): K030682

Device Name: Calcium Hydroxylapatite Implant

Indications for Use:

BioForm's Calcium Hydroxylapatite Implant is intended to fill and/or augment dental intraosseous and oral/maxillofacial defects including:

- Periodontal Defects
- Ridge Augmentation
- Extraction Sites
- Craniofacial Augmentation
- Cystic Defects

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X *or* Over-the-Counter Use _____
(Per 21 CFR 801.109)

Optional Format 1-2-96

Kan Mulay for ASR
(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K030682